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PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

10 JUN 1999

WRITTEN OPINION
BROOKES & MARTIN

(PCT Rule 66)

Date of mailing
(day/month/year)

08.06.99

Applicant's or agent's file reference

DCW/SH

REPLY DUE

within 3 month(s)
from the above date of mailing

International application No.

PCT/GB98/02713

International filing date (day/month/year)

09/09/1998

Priority date (day/month/year)

12/09/1997

International Patent Classification (IPC) or both national classification and IPC

A61B19/08

Applicant

KCI MEDICAL LIMITED et al.

1. This written opinion is the first drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain document cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.


When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 59.8 and 66.3.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 12/01/2000.

Name and mailing address of the international
preliminary examining authority:

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WRITTEN OPINION

I. Basis of the opinion

1. This opinion has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, pages:

1-9 as originally filed

Claims, No.:

1-6 as originally filed

Drawings, sheets:

1/4-4/4 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees, the applicant has:

- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with for the following reasons

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and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:
see separate sheet

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:

- ☒ all parts.
☐ the parts relating to claims Nos. .

V. Reasoned statement under Rule 68.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims
Inventive step (IS)	Claims 6
Industrial applicability (IA)	Claims

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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To point IV:

1. The requisite unity of invention (Rule 13.1 PCT) does not exist inasmuch as a technical relationship involving one or more of the same or corresponding special technical features in the sense of Rule 13.2 PCT does not exist between the subject-matter of independent claims 1 and 6.

- 1.1 The separate inventions are:

- a)- a suction head for applying suction to a wound area; and
- b)- a surgical drape.

To point V:

2. Reference is made to the following documents:

D1: US - A - 5 437 622

D2: WO - A - 97/18007

D3: EP - A - 0 117 632

3. Claims 1-5 satisfy the criteria of Article 33 PCT.

4. As far as it can be understood (see point 11 below), the subject-matter of independent claim 6 does not involve an inventive step (Article 33(3) PCT), for the following reasons:

- 4.1 Document D1 (cf. Fig.1; column 3, lines 20-27; 50-column 4, line 2) which is considered to represent the most relevant state of the art, discloses a surgical drape which comprises a flexible, adhesive-coated plastics film (1) and a strengthening layer (2) applied to the face opposite to the adhesive coating, the strengthening layer (2) being a plastics film which is less flexible than said adhesive-coated film (1), and a protective, releasable layer (3) applied to the adhesive coating, the drape having at least one first edge having a non-adhesive coated handling bar (4) for separating the adhesive-coated film (1) from the protective layer (3), from which the subject-matter of claim 6 differs in that:

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- a)- the drape has an aperture through at least the strengthening film and adhesive-coated film to permit, in use, access to a wound area; and
- b)- the protective layer comprises a separate strip extending parallel to the first edge of the drape, which protects the adhesive coating in the region of the aperture and carries at least one flap overlapping the adjacent portion of the protective layer, said flap constituting a handle for facilitating removal of said strip prior to use.
- 4.2 The problems to be solved by the invention claimed in claim 6 may therefore be regarded as:
- a)- to provide a surgical drape which is suitable to accommodate a suction head for applying suction to a wound area; and
- b)- to improve the handling of the surgical drape.
- 4.3 The solution proposed in claim 6 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
- the features mentioned under points 4.1 a) and b) above have already been employed for the same purpose in similar surgical drapes, see documents D2 (cf. Fig. 7a, 7b; page 8, line 13-page 9, line 9) and D3 (cf. Fig. 1; abstract). The skilled person would therefore regard it as a normal option to include these features in the surgical drape described in document D1 in order to solve the problems posed.
5. In order to overcome the objection of lack of inventive step, it seems appropriate to file an amended claim 6.

To point VII:

6. Independent claims 1 and 6 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (documents D1 and D2) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).

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- 6.1 Claim 1: in the present case, the following features are known in combination from the document D2 (cf. Fig. 6a,6c; page 8, lines 5-13) and belong in the preamble of such a claim:

- a suction head for applying suction to a wound area which comprises a generally planar flange portion and a tubular connector piece on a first face for connecting a suction tube to an aperture through the flange portion to the other face.

- 6.2 Claim 6: the following features are known in combination from the document D1 and belong to the preamble of such a claim:

- a surgical drape which comprises a flexible, adhesive-coated plastics film and a strengthening layer applied to the face opposite to the adhesive coating, the strengthening layer being a plastics film which is thicker or less flexible than said adhesive-coated film, and a protective, releasable layer applied to the adhesive coating, at least one first edge of the drape having a non-adhesive coated handling bar for separating the adhesive-coated film from the protective layer.

- 6.3 Independent claims 1 and 6 should therefore be redrafted accordingly.

7. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
8. While filing amended claims it should be taken into account that the description should be in conformity with the claims (Rule 5.1a(iii)).
9. According to the requirements of Rule 11.13(i) reference signs not appearing in the description shall not appear in the drawings, and vice versa. This requirement is not met in view of the reference sign 26 (cf. Fig. 3,4; page 7, lines 5-7).

To point VIII:

10. The expression "generally" on line 2 of claim 1 does not introduce any limitation in the scope of the claim according to the PCT-Guidelines III-4.6.

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11. The following relative term "thin" used in claim 6, line 1, has no well-recognised meaning and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claim unclear (Article 6 PCT).